

Add claims 61 - 98 to read as follows:

a' 323
n 2
61. An anti-infective medical device, comprising a polymeric matrix containing within the matrix an oxidant-producing component that when wetted causes the formation of an oxidant and sustained release of the thus-formed oxidant into and about the polymeric matrix so that the matrix serves as an anti-infective reservoir.

62. The anti-infective medical device of claim 61 where the oxidant is elemental iodine.

63. The anti-infective medical device of claim 62 where the oxidant-producing component comprises a reducing agent and an oxidizing agent.

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n 2
64. The anti-infective medical device of claim 63 where the oxidant-producing component further comprises a proton donor that, in combination with the reducing agent and the oxidizing agent, forms solid particles dispersed within the polymeric matrix in sufficient amount to provide anti-infective activity to the medical device.

65. The anti-infective medical device of claim 63 where the reducing agent is a water soluble iodide salt.

66. The anti-infective medical device of claim 65 where the reducing agent is an alkali iodide salt.

67. The anti-infective medical device of Claim 66 where the alkali iodide salt has a concentration of about 0.01% to about 16% by weight of the polymeric matrix.

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B3/ 68. The anti-infective medical device of claim 63 where the oxidizing agent is selected from the group consisting of anhydrous alkali iodine oxide salts, iodine pentoxide, inorganic and organic peracids, oxidase enzymes, and combinations thereof.

69. The anti-infective medical device of claim 68 where the oxidizing agent is selected from the group consisting of alkali iodate salts, iodine pentoxide, and mixtures thereof.

al cont 70. The anti-infective medical device of claim 64 where the proton donor is selected from the group consisting of organic acids, inorganic acids, iodine pentoxide, and other acid anhydrides.

71. The anti-infective medical device of claim 70 where the proton donor is selected from the group consisting of perborates and organoperoxy acids.

72. The anti-infective medical device of claim 71 where the proton donor has a concentration of from about 0.01% to about 16% by weight of the polymeric material.

73. The anti-infective medical device of claim 64 where the proton donor is a hydrogen peroxide-generating oxidase enzyme selected from the group consisting of glucose oxidase and diamine oxidase.

74. The anti-infective medical device of claim 73 where the glucose oxidase has a specific activity of from about 2,000 IU/g to about 200,000 IU/g, the diamine oxidase has a specific activity of from about 50 IU/g to about 800 IU/g, and the concentration of the glucose oxidase or diamine oxidase is from about 0.01% to about 2.5% by weight of the polymeric material.

75. The anti-infective medical device of claim 73 further comprising a peroxidase enzyme, where the glucose oxidase or diamine oxidase concentration is at least about 0.01% by weight of the polymeric matrix, the peroxidase enzyme is present at a concentration of at least about 0.01% by weight of the polymeric matrix, and the sum concentration of the oxidase and peroxidase enzymes is from of about 0.02% to about 2.5% by weight of the polymeric matrix.

21 cont

76. The anti-infective medical device of claim 61 where the polymeric matrix comprises a hydrophobic polymer selected from the group consisting of polyureas, polyurethanes, poly(ethylene/vinyl acetate), polyvinylchloride, polyesters, polyamides, polycarbonate, polyethylene, polypropylene, polystyrenes, polytetrafluoroethylene, and [silicone polymers].

end

→ 77. The anti-infective medical device of claim 61 where the polymeric matrix comprises a hydrogel formed from a hydrogel agent selected from the group consisting of linear polyacrylates, cross-linked polyacrylates, hydroxyalkyl celluloses, polycarboxyalkyl celluloses, water soluble cellulose, polyvinyl alcohol, chitosan polymers, salts of alginic acid, starch, and combinations thereof.

78. The anti-infective medical device of claim 77 where the hydrogel has a pH between about 3.0 to about 6.5.

79. The anti-infective medical device of claim 78 where the hydrogel has a pH about 4.0.

80. The anti-infective medical device of claim 77 where the concentration of the hydrogel agent is about 0.2% to about 5% by weight of the hydrogel.

81. The anti-infective medical device of claim 80 where the concentration of the hydrogel agent is about 2% by weight of the hydrogel.

82. The anti-infective medical device of claim 77 where the oxidant-producing component comprises an oxidizing agent selected from the group consisting of alkali iodine oxide salts.

83. The anti-infective medical device of claim 82 where the oxidizing agent has a concentration in the hydrogel of from about 0.1 mM to about 200 mM.

84. The anti-infective medical device of claim 77 where the oxidant-producing component comprises a hydrogen peroxide-generating oxidase enzyme having a concentration in the hydrogel of from about 2 µg/ml to about 500 µg/ml and a peroxidase enzyme.

85. The anti-infective medical device of claim 84 where the peroxidase enzyme has a specific activity of about 250,000 IU/g to about 330,000 IU/g, and a concentration in the hydrogel of from about 2 µg/ml to about 500 µg/ml.

86. The anti-infective medical device of Claim 77 where the oxidant-producing component comprises a hydrogen peroxide-generating oxidase enzyme, a peroxidase enzyme, and a water soluble iodide salt having a concentration in the hydrogel of about 0.1 mM to about 200 mM.

87. The anti-infective medical device of claim 84 where the polymeric matrix includes a substrate which is oxidized by the oxidase enzyme.

~~88.~~ An anti-infective medical device prepared from a polymeric material, comprising

- a) a reservoir chamber allowing for release of fluid contained within the reservoir chamber to the exterior surface of the device on physical distortion of the device; and
- b) an fluid oxidant-producing component held within the reservoir chamber, such that physical distortion of the device causes the oxidant-producing component to release to the exterior surface of the device causing formation of an oxidant and sustained release of the thus-formed oxidant.

89. The anti-infective medical device of claim 88 where the oxidant is elemental iodine.

90. The anti-infective medical device of claim 89 where the oxidant-producing component comprises a water soluble iodide salt and an oxidizing agent.

91. The anti-infective medical device of Claim 90 where the oxidizing agent is selected from the group consisting of alkali iodine oxide salts, peracids, and hydrogen peroxide-generating oxidase enzymes.

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134 ~~92. The anti-infective medical device of claim 61 that is selected from the group consisting of catheters, guidewires, gloves, prostheses, implants, and contraceptive devices.~~

~~93. The anti-infective medical device of claim 76 that is selected from the group consisting of catheters, guidewires, gloves, prostheses, implants, and contraceptive devices.~~

cont
BY 94. The anti-infective medical device of claim 77 that is selected from the group consisting of catheters, guidewires, gloves, prostheses, implants, and contraceptive devices.

95. The anti-infective medical device of claim 61 where the device is configured for vaginal implantation, and the oxidant is formed in a concentration from about 5 ppm to about 100 ppm to provide spermicidal activity to the medical device.

96. The anti-infective medical device of claim 76 where the device is configured for vaginal implantation, and the oxidant is formed in a concentration from about 5 ppm to about 100 ppm to provide spermicidal activity to the medical device.

97. The anti-infective medical device of claim 77 where the device is configured for vaginal implantation, and the oxidant is formed in a concentration from about 5 ppm to about 100 ppm to provide spermicidal activity to the medical device.

98. The anti-infective medical device of claim 88 where the device is configured for vaginal implantation, and the oxidant is formed in a concentration from about 5 ppm to about 100 ppm to provide spermicidal activity to the medical device.

REMARKS

Entry of this amendment is respectfully requested. No new matter is added by this amendment because the added claims are fully supported by the application as filed.

Claims 61-98 are in this application; claims 1-60 having been canceled and claims 61-98 having been added by this response. Claims 1-60 were subject to restriction.